

Life Sciences Business Architecture Model (LS BAM)

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Translational Research in Medicine Business Architecture Model (BAM)

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The Translational Research in Medicine Business Architecture Model (BAM) is designed to describe the activities, goals, and people involved in translational research, including clinical trials, laboratory research, and the organizational needs required to support these activities. The model will include diagrams and descriptions (often called process maps that make up an overall model) that show how translational research is generally done. For example, initial process maps for clinical research include developing an initial clinical study plan, conducting the clinical study with patients, and then writing up the results of that study. Process maps in the area of life sciences (which include biospecimen management and genomic research) are also in early development.

The business stakeholder scope of the model spans the [National Cancer Institute](#), [Cooperative Groups](#), Cancer Centers, Community Clinical Oncology Programs (CCOP), and the broad translational research community. The objective of this effort is to identify the business use cases (activities), analyze the use cases and processes, and build a comprehensive business architecture model of the translational research domains.

The BAM modeling effort is facilitated by analysts who work to harmonize content provided by subject matter experts with existing resources and other caBIG® initiatives such as the Cancer Data Standards Repository ([caDSR](#)), Biomedical Research Integrated Domain Group ([BRIDG](#)), [Life Sciences Domain Analysis Model \(LS DAM\)](#), as well as extramural activities like Health Level 7 ([HL7](#)) and the Clinical Data Interchange Standards Consortium ([CDISC](#)).

While the ultimate goal is to develop a complete representation of translational research encompassing basic research to clinical trials, an iterative methodology is being followed. Through content capture, review, and refinement, the caBIG® Clinical and Life Sciences Domains aim to achieve a model that represents the processes, interactions, and interoperability scenarios that occur in the planning, initiation, conduct, reporting, and analysis of biomedical research. From this model, the workspaces aim to facilitate gap analysis of functionality in the current [caBIG® Clinical Trials Suite](#) and [LSD Life Sciences Distribution](#) and map caBIG® solutions to biomedical research business needs.

Your feedback and input on the BAM is always appreciated. Please feel free to send any comments to Michele Ehlman at michele.ehlman@nih.gov.

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Current Life Science BAM Release v1.1

Use Case Web Views

[Life Science Biomedical Research Architecture Model Version 1.1](#) Released 14 June 2010 (Please use Internet Explorer to view.)

Use Case Specification

[Life Science Biomedical Research Architecture Model Version 1.1 Report PDF](#) Released 14 June 2010

[Life Science Biomedical Research Actors Version 1.1 Report](#) Released 14 June 2010

Enterprise Architect File

[Life Science Biomedical Research Architecture Model Version 1.1 EA file](#) Released 14 June 2010

Life Science Activity Diagrams

[Life Science BAM Activity Diagram for Sample Flow](#) Released November 2010

[Life Science BAM Activity Diagram for NextGeneration Sequencing](#) Released November 2010

[Life Science BAM Activity Diagram for Proteomics](#) Released February 2011

[Life Science BAM Activity Diagram for Proteomics \(User Version\)](#) Released February 2011

[Life Science BAM Activity Diagram for Proteomics \(Interactive HTML\)](#) Released February 2011 (Please use Internet Explorer to view)

[Life Science BAM Activity Diagram for Laser Capture Microdissection](#) Released February 2011

[Life Science BAM Activity Diagram for Laser Capture Microdissection \(User Version\)](#) Released February 2011

[Life Science BAM Activity Diagram for Laser Capture Microdissection \(Interactive HTML\)](#) Released February 2011 (Please use Internet Explorer to view)

Archived Life Science BAM Release(s)

Use Case Web Views

[Life Science Biomedical Research Architecture Model Version 1.0 HTML](#) Released 15 February 2010 (Please use Internet Explorer to view.)

Use Case Specification

[Life Science Biomedical Research Architecture Model Version 1.0 Report PDF](#) Released 15 February 2010

Enterprise Architect File

[Life Science Biomedical Research Architecture Model Version 1.0 EA file](#) Released 15 February 2010

Business Architecture Documentation

Frequently Asked Questions

For more information on business architecture modeling, please consult our Introduction to Biomedical Research Business Architecture Model page: [BAM FAQ](#)

Glossary

For more information on terms and definitions on the Biomedical Research Business Architecture Model, please consult our Biomedical Research Business Architecture Model Glossary of Terms and Definitions page: [BAM Glossary](#)

Biomedical Research Business Architecture Model

We welcome you to review the use cases in development.

The model is represented in the wiki for ease of review - this is a work in progress:
[Translational_Research_in_Medicine_Business_Architecture_Modeling](#)

Modeling Activity Areas

To help with organization of this model, we have grouped the activities into three high-level categories and then by a logical segmentation. These categories are not meant to imply any process or chronology. They are merely an organizational artifact to logically group the use cases.

Life Science Research

Plan Research: This section includes the activities for the planning of research in the field of Life Sciences. The planning includes the concepts for formulating a problem or hypothesis, choosing the appropriate experimental methodologies and/or analysis tools, and identifying general resources that may be needed to perform the experiments.

Perform Research: This section includes the activities for performing research by first setting up the experimental system and then executing planned experiments using the system.

Analyze and Synthesize Results: This section includes activities for analyzing raw and primary data sets (e.g., quantitative, qualitative, and/or qualitative results that have been quantified); generating processed data sets; evaluating and interpreting the observations and outcomes of experimentation; and, for hypothesis testing studies, the activities for accepting or rejecting the hypothesis.

Disseminate Results and Artifacts: This section includes activities for sharing and publishing the scientific raw and processed data and interpretations of the observations and the data.

Clinical Research

Plan Study: Develop, document and maintain the scientific, regulatory, financial, legal and logistical (including the protocol processes and resources) aspects of a protocol.

Initiate Study: Complete the regulatory, financial and logistical requirements to activate the study for site participation and open the study at the sites for subject enrollment. This applies to both the Coordinating Center and Participating Sites. This includes all updates (amendments) to the study.

Conduct Study: Includes all the activities involved in execution of a study, i.e., from the time the study is made available for enrollment until end of study when data collection is complete. This applies to both the coordinating center and participating sites.

Report and Analyze Study: Develop and provide an organized collection of information to authorized stakeholders in support of execution of the protocol statistical plan, subject safety and regulatory requirements.

Common For Research

Supporting Use Cases: These use cases include the activities for managing the common resources that are needed across biomedical research. This section address activities for managing the organization, person, clinical protocol, research material, and security and data access.

Biomedical Research Actors: An actor is a role played within a process or a user of the system, where "role" or "user" can mean a human being, an organization, a machine, or even another system. Anything that participates in the process or interacts with the system from the outside or from a system boundary is termed an actor. Actors are typically associated with use cases.

Modeling Activity Status

The Biomedical Research Business Architecture Model use cases are in varying stages of development. Use case statuses are defined below:

- **Placeholder:** Use cases identified during a working group that are outside the scope of the working group.
- **Working_Group:** Use cases that are currently being defined by a working group or project team.
- **In_Workspace_Review:** Use cases that are being reviewed by the appropriate Workspace community.
- **Workspace Reviewed:** Use cases that have been reviewed by the appropriate Workspace community.
- **Released:** Use cases that have been reviewed by the appropriate Workspace community and released in a version.